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|--|------------------------------------|---------------------------------------|----------------------|------------------|--|
| APPLICATION NO.  | FILING DATE                        | FIRST NAMED INVENTOR                  | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |  |
| 10/695,030   | 10/28/2003                         | Ross Mitchell Blanton                 | 01057                | 5700             |  |
| 35467<br>BIOMERIEU∑  | 7590 10/04/2007<br><b>(, INC</b> . |                                       | EXAMINER             |                  |  |
| PATENT DEP<br>100 RODOLPI  | ARTMENT                            |                                       | LEVKOVICH, NATALIA A |                  |  |
| DURHAM, NO   | -                                  |                                       | ART UNIT             | PAPER NUMBER     |  |
| , the state of the |                                    |                                       | 1743                 |                  |  |
|  | •                                  | •                                     |                      |                  |  |
|  |                                    |                                       | MAIL DATE            | DELIVERY MODE    |  |
|  |                                    |                                       | 10/04/2007           | DADED            |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary  |   | Application No.   | Applicant(s)          |  |  |
|--|---|---|-----------------------|--|--|
|  |   | 10/695,030  | BLANTON ET AL.        |  |  |
|  |   | Examiner  | Art Unit              |  |  |
|  |   | Natalia Levkovich   | 1743                  |  |  |
| <br>Period for I   | The MAILING DATE of this communication appo<br>Reply  | ears on the cover sheet with the c  | orrespondence address |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |   |                       |  |  |
| Status   |   |   |                       |  |  |
| 1)⊠ R  | esponsive to communication(s) filed on 18 Ju  | l <u>y 2007</u> .   |                       |  |  |
| 2a)∏ TI  | This action is FINAL. 2b)⊠ This action is non-final.  |   |                       |  |  |
| 3)∏ Si   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                       |   |                       |  |  |
| cle  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |                       |  |  |
| Disposition  | of Claims   |   |                       |  |  |
| <ul> <li>4) ☐ Claim(s) 1-25 is/are pending in the application.</li> <li>4a) Of the above claim(s) 14-17 and 25 is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 1-13 and 18-24 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) 1-25 are subject to restriction and/or election requirement.</li> </ul>  |   |   |                       |  |  |
| Application  | Papers  |   |                       |  |  |
| 9) ☐ The specification is objected to by the Examiner.  10) ☑ The drawing(s) filed on 10/28/2003 is/are: a) ☐ accepted or b) ☑ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |   |                       |  |  |
| Priority und   | ler 35 U.S.C. § 119   |   |                       |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |   |                       |  |  |
| Attachment(s)  |   |   |                       |  |  |
| 1) Notice o 2) Notice o 3) Informat  | References Cited (PTO-892)  f Draftsperson's Patent Drawing Review (PTO-948)  ion Disclosure Statement(s) (PTO/SB/08)  o(s)/Mail Date | 4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te                    |  |  |

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#### **DETAILED ACTION**

### Election/Restriction

1. Election of claims 1-13 and 18-24 (Group I), made without traverse in the reply filed 07/16/2007, is acknowledged.

### **Drawings**

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'single longitudinal axis' between the stations and the sensor station must be clearly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional

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replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 24 recites a separate sensor station. Examiner found no support for this limitation in the specification.

# Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 1-13 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites a vacuum station 'adapted for manual insertion' of the sample carrier. It is unclear as to what structural features of the vacuum station allow the manual insertion. It is also unclear whether by 'manual' Applicant means the insertion done by hand, or the insertion involving some other human efforts or skills (as opposed to fully automated insertion). The same consideration applies to claims 10-11.

Claim 1 also recites the vacuum source being controlled so as to load test samples from individual fluid receptacles into respective test sample devices. It is unclear whether or not this means involvement of a controlling device. See also claim 10.

Additionally, in line 11, claim 1 recites the processing subsystem being 'remote' from the vacuum station, which is a relative term. Also see claims 5, 10, 11.

Claim 9 recites a set of panels 'forming a front portion of the instrument'.

The claim further recites a user interface. The front of the instrument formed by the panels is adapted to be observed ['faced'] by a user. In this connection, it is unclear what structural features distinguish one user interface (front panels) over the other.

With respect to claims 18 and 20, it is unclear what structural elements of the cover panel would provide the 'access for a thermometer'.

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. Claims 1-13 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanning et al. (US 5869006).

With respect to claims 1-10, 13 and 22, Fanning discloses a sample testing machine comprising, as shown in Figures 1, 1A and 2, boat 22 ['carrier'], vacuum station 400 and several sample processing stations ['modules'], including optical station 800, sealing station 500, incubation station 600 with carousel load ['autoloading station'], disposal station 900, as well as transport system connecting the stations (see Abstract).

Fanning does not teach the boat to be loaded manually into the vacuum station. However, non-automatic sample loading into vacuum chambers is well known in the art. It would have been within the ordinary skill of an artisan at the time the invention was made to have employed a number of non-automatic operations (including loading of the vacuum station) in the modified automatic

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apparatus of Fanning, in order to gain more flexibility for user input and to simplify controlling sub-systems, which would also reduce the overall cost of the apparatus. It would have been also obvious for such modification to arrange several secured doors in the vacuum chamber, in order to monitor pressure during accessing the vacuum station, or in loading / unloading /disposal stations, for the ease of maintenance.

Referring to claim 7, note that the multi-well cards are not accorded patentable weight, since they are not positively recited as a part of the claimed invention. The same consideration applies thermometer of claims 18-21.

With respect to claims 9, 18 and 20, Fanning teaches that the apparatus has "a user friendly and attractive panel covering for aesthetic and safety purposes" as well as a user interface "connected to the machine's host CPU" (Col. 23, lines 18 plus).

Regarding claim 12, the boat is motor driven, the drive constituting the 'carrier engaging member'.

Addressing claims 19 and 21, Fanning does not teach air distribution system for the incubation station. However, such system are common in the art. It would have been within the ordinary skill in the art to have employed such system in the modified apparatus of Fanning, in order to provide optimal conditions for the incubation process which would require oxygen supply.

#### Conclusion

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9. Any inquiry concerning this communication or earlier communications from

the examiner should be directed to Natalia Levkovich whose telephone number is

571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax

phone number for the organization where this application or proceeding is

assigned is 571-273-8300.

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free).

Jill Warden
Supervisory Patent Examiner

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